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Statement of

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INTRODUCTION

Madame Chairwoman and Members of the Committee, I am Benjamin L. England, an attorney in the Washington, D.C. offices of the law firm of Jones Walker. I am a 17-year veteran of the U.S. Food and Drug Administration (FDA), during which time I held the positions of Regulatory Microbiologist in FDA's Baltimore Microbiology Laboratory, Consumer Safety Officer and Compliance Officer in FDA's Baltimore District Office, Special Agent with FDA's Office of Criminal Investigations in the Miami Field Office, Compliance Officer in FDA's Miami Resident Post, and Regulatory Counsel to FDA's Associate Commissioner for Regulatory Affairs (or ACRA)in Headquarters. I resigned my most recent FDA position as Regulatory Counsel to the ACRA in July 2003 -- a position I held in FDA for over three years as a Title 42 appointee. During my last three years at FDA, I was a key point person for Customs and Border Protection, I chaired the FDA's Counterfeit Drug Working Group, instituted the Joint Agency-Industry Working Group to combat product counterfeiting and tampering, which laid the ground

work for the preparation of FDA's initial Counterfeit Drug Task Force report, and co-chaired FDA's Import Strategic Plan Steering Committee. I am now in private practice representing domestic and foreign companies before and against various federal agencies related to the manufacture, distribution, importation and exportation of FDA and USDA regulated commodities. I spend much of my time assisting foreign companies and importers in complying with the myriad of federal and state regulatory requirements prior to the process of importation into the U.S.

With me here today, and also available to answer your questions, is Mr. Carl R. Nielsen, who has been my friend and colleague in FDA and now outside for the last 17 years. Mr. Nielsen is a retired 28-year veteran of the FDA and knows more about that Agency and its operations, policies, and procedures than any single person I know. Mr. Nielsen retired from FDA in February 2005 and now is a consultant for foreign and U.S. companies assisting them with FDA compliance matters through the consulting practice, FDAImports.com, Inc. Mr. Nielsen has performed many important functions throughout his extensive FDA career. Most notably, for today's purposes, Mr. Nielsen was primarily responsible for the successful criminal prosecution of a number of complex cases involving imitation controlled substances and international bulk drug counterfeiters prior to the creation of the Office of Criminal Investigations in 1992. He was one of the first FDA supervisors to successfully separate the District's Import Operations from its domestic operations, enabling a specific inspection and compliance team to focus upon import issues, he arranged for the collocation of FDA's import inspection team at the port, with Customs, and finally retired from FDA as the Director of the Division of Import Operations and Policy; a position he held for six years.

Mr. Nielsen and I established the Agency's first series of Import Enforcement Training Courses, and with a few dedicated FDA and Customs officials, trained nearly every FDA import inspector, investigator, import program manager, and compliance officer in the effective use of Customs enforcement tools against products imported in the U.S. in violation of FDA requirements.

FDA's Current Import Program and its Challenges

FDA designed its current import program in the 1970s based upon a century old statutory regime. When section 801 of the Food Drug & Cosmetic Act (FDCA) was enacted very few FDA-regulated products were imported into the U.S. Prior to NAFTA and other free trade agreements entered into by the United States, the majority of FDA-regulated imports consisted of ingredients and components intended for further domestic manufacturing. The most common inbound shipment consisted of break bulk (or noncontainerized) cargo arriving at seaports. The primary strategy at that time was to examine and test some products at the border but to primarily rely on FDA's domestic inspections to evaluate the quality of imported ingredients and components. Today, approximately 35% of imported shipments arrive by air; 35% by road; 24% by sea, and 5% by rail. The 300+ U.S. Customs ports of entry are not just around the perimeter of the country at seaports. They are also strewn along the southwest and northern land borders and deep in the country's interior; in places like Chicago and Omaha.

According to FDA data, from 1991 to 2000 FDA-regulated imports increased by 272% and in 2001 alone there were more than 7 million imported commercial lines of entry. In 2002, approximately 7.8 million lines of FDA-regulated commercial shipments were imported. From 1997 to 2002, the number of imports of every kind of FDA-regulated product at least doubled. This year, in 2007, FDA anticipates as many as 18 million commercial lines of entry under its

jurisdiction will be imported – representing a second doubling in sheer volume since 2002. FDA's resources directed at assessing the safety of imported products has remained static throughout the entire time period.

Since 1993, finished-product manufacturing in many FDA-regulated industries has shifted to foreign markets. Now the answers FDA used to obtain about the quality and safety of ingredients through its domestic inspections of importers lay thousands of miles beyond U.S. borders – and far beyond traditional FDA oversight. Yet FDA has continued to rely primarily on border examinations and finished product testing to identify problems with imported product. Finished product testing at the border is not statistically valid to predict the safety of shipments that are not tested or to predict the quality of future shipments – even from the same processor. This is particularly the case when FDA examines and tests such a miniscule percentage of imported shipments. FDA may imply that its electronic screening system is assisting in assuring the safety and compliance of imported products – but it is not. FDA's screening system, the Operational and Administrative System for Import Support (or OASIS), is a static, hard rules based system. It only looks for things it is specifically instructed to look for among data elements derived primarily from an invoice, shipping manifest or bill of lading. Such documents simply do not contain information about the manner in which a product was manufactured or the ingredients or components used to prepare the product.

The most common OASIS preset screening combinations are shipper or manufacturer identity and product code or country or region and product code. These data combinations are used to implement FDA's import alert system. However, even when an import alert "hits" in the system, a human, an entry reviewer, must physically read through dozens of pages and scour through perhaps hundreds of written data elements to see if OASIS is correct before

automatically detaining a shipment based upon the alert. OASIS is not integrated with other FDA legacy systems; therefore, inspectors, entry reviewers and compliance officers must enter and exist dozens of data bases in any given hour to determine whether OASIS data is accurate and truly applicable to an imported shipment. The waste in full time equivalents is massive. OASIS assists in work flow and tracks import transactions, but it performs no affirmative compliance or safety assessment.

FDA's oft repeated lament regarding its failure to institute significant change in its import program is lack of sufficient resources. No doubt there is truth in this complaint. However it is neither new nor unpredictable and throwing more money at an unflinching FDA fails to address the fundamental problems with FDA's import philosophy. These import challenges did not arise recently, as the data clearly proves. Yet contrary to all logic a post-NAFTA FDA continued to pursue a doomed pre-NAFTA paradigm. It is even more troubling that FDA has failed to implement literally hundreds of proposed solutions to specific import problems which would have enabled FDA to begin to progressively focus its limited resources where the risks are indeed greatest. Those proposals were made internally through the Import Strategic Plan (ISP) over four years ago. In the meantime, FDA regulated imports again increased from approximately 10 million to 18 million commercial lines of entry. Given these circumstances, increasing funding to support FDA's current import paradigm without requiring significant change in its approach would produce far too much additional waste, result in even more shipping delays for compliant and safe import shipments – even from China, and provide little basis for consumer (or congressional) confidence in the safety of imported products. Attempting to build on existing efforts and operations is predestined to fail because it would be based upon too many false presumptions. A drastic internal change is needed. I agree with this

Subcommittee's recommendation that any increase in resources should be made available to FDA only as the Agency defines the problems and provides a coherent plan to solve them.

The Bioterrorism Act

The statutory framework covering FDA authority over imported articles remained substantially unchanged for nearly 100 years. However, in response to the tragic events September 11, 2001, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act") (PL 107-188). On June 12, 2002, President George W. Bush signed the Bioterrorism Act into law and dramatically enhanced FDA's import authority for imported foods.

Most notably, section 302(a) of the Bioterrorism Act amended Section 801 of the FDCA directing FDA to give "high priority to increasing the number of [import] inspections . . . for the purpose of enabling [the agency] to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of [imported] food." Furthermore, section 302(b) directs FDA to "improve its information management systems that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of [FDA] to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with [the FDCA]." These two legislative mandates essentially establish the framework and the context within which the balance of the new food safety and security authorities were to be implemented. More significantly, these subsections provided a blueprint for the agency to redesign its import policies, programs, and operations through the ISP process. Instead, we got Prior Notice. Now food importers provide the same invoice and shipping data elements, plus some additional registration data – earlier. As I often asked while still at FDA, "if invoice data

provides little in the way of risk assessment today, why would I want it yesterday? What am I supposed to do with that data?"

Missed Opportunities for Change

To justifiably increase public confidence in imported product safety, FDA must rely upon the cumulative effects of a variety of risk-based strategies – some traditional and some new – which may be operationally integrated with a robust information technology system. However, it is critically important to first properly define the problem before looking for solutions. For instance, far too often data about imported trade and our trading partners is misunderstood and therefore misused. It has been recently reported that the top five exporting countries to the United Sates are Canada, China, Mexico, Japan, and Germany. The fact that China appears so high on this list created consternation, and perhaps it should. However, the sum of Canadian and Mexican shipments amounts to nearly 50% of the total of our top five trading partners. Our nearest and most trusted trading partners to the north and south represent a field of harvest for opportunities to mitigate the risks related to a substantial portion of imported goods.

Shortly after September 11, 2001, FDA's Leadership Council established an Import Strategic Plan Steering Committee. By spring 2003 the Import Strategic Plan was virtually complete. FDA developed the ISP from the contributions of more than one hundred Agency experts in all product Centers, field and headquarters components, laboratories, international programs staff, the General Counsel's Office and the Office of Policy, Planning and Legislation.

The ISP's principles were simple but far reaching: Push the current FDA import evaluation process from the extremely limited border transaction to a life-cycle process, which:

- Intentionally gleans information from all points along an article's supply chain;
- Assesses that information based upon FDA requirements and risk of harm;

- Delivers the assessment to border inspectors, compliance officers, and electronic screening systems for reliable targeting decisions; and
- Results in the facilitation of safe products and enforcement against products that are unsafe.

Under the ISP, three subcommittees were created to assess import safety risks and propose agency solutions along the component parts of the international supply chain, including: foreign operations, border operations and domestic operations. Two cross cutting subcommittees were tasked with tying these supply chain components together: Information Technology and Applied Science and Technology. Each committee was to find information FDA could use to assess risk and develop solutions for mitigating risk earlier in the supply chain rather than later. Meanwhile, the IT and Science subcommittees identified solutions implementing the proposals and reducing time frames where risk targeting indicated a need to inspect and test incoming goods. At the request of the Leadership Council, the ISP subcommittees and steering committee value-ranked the proposed action items for enhancing import safety and estimated their costs.

The significance of the ISP and its hundreds of proposed action items rests in what it represents: an internal agency demand for a dramatic shift in thinking about the identification, assessment and mitigation of risks in the international supply chain. Many of the ISP proposals are indeed costly. However, many could have been implemented nearly immediately and would have begun the process of increasing FDA's import efficiency and effectiveness using existing resources. It is this shift in thinking that FDA's middle and upper management has resisted. But I believe that all involved in the ISP process recognized the import problems – even in 2003— are complex and cannot be solved with FDA's traditional regulatory approaches and philosophy.

Some Proposed Changes Going Forward

First, we believe any action by this Subcommittee should include a significant resource investment targeted directly for reengineering FDA's stove-piped IT systems. IT improvements recommended in the ISP are a contingency for executing any serious risk-targeting strategies.

Second, we recommend the establishment within FDA of an organization reporting to the Commissioner with the mission of focusing on enhancing the safety of imported products. We believe fixing FDA's import problem requires it be broken free from the domestic programs, which produce much of the bureaucratic inertia against change in this area. A new organization would enable proper staffing, allocation of human resources at ports of entry, management and implementation of ISP-based strategies. It should be responsible for all import and international focused work-planning activities; conducting facility inspections of foreign processors and importers; overseeing and conducting border operations; conducting foreign government and industry assessments and training; and support trade negotiations in a manner to enhance safety of imported products. To accomplish this, the new organization should be directly funded, rather than receiving its funding through the product Centers.

Third, section 302(b) of the Bioterrorism Act, which enabled FDA to implement risk-based strategies for managing food imports, should be expanded to cover all other FDA-regulated products.

Fourth, FDA should publish and begin implementing the ISP in accordance with the plan's guiding principles, goals, and themes.

Fifth, FDA should begin developing third party inspection and certification programs, accompanied by a robust auditing process, to enable facilitation of imported products that are likely to have been manufactured in accordance with FDA safety principles. This would permit

the agency to focus its most earnest import inspection and examination efforts on shipments representing known and unknown risks.

Sixth, FDA requires additional resources to conduct more foreign inspections and import examinations and product sampling, and to develop and publish meaningful Agency guidance relating to identifying and managing risks in the full life cycle of imported products.

Seventh, FDA should rely on Customs and Border Protection and the Department of Homeland Security (DHS) to manage security risks associated with FDA regulated imports. DHS' security programs should be expanded to incorporate product security risks, rather than focusing solely upon the security of in-transit cargo or inbound containers.

Eighth, FDA should be prevented from pursuing any aspect of its Reorganization Plan absent some reliable evidence of cost savings without affecting the public health and the agency's service to the importing community. Reorganization elements that should be prevented prior to an objective third party assessment include: (a) Closure of the Agency's laboratories; (b) Realignment of FDA Districts or existing Laboratories; (c) Realignment of agency compliance or inspection functions across or among Districts or Regions; and (d) Consolidation or centralization of FDA's import entry review functions.

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Mr. Nielsen and I thank the Subcommittee Chairwoman and Members for the opportunity to discuss these import issues and we look forward to answering any questions.